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Applicants: Thomas D. Lyster et al.

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For : METHOD AND APPARATUS FOR DEFILLIBRATING PATIENTS OF ALL AGES

DECLARATION UNDER 37 CFR §1.132

I, CARLTON B. MORGAN, am a scientist with the Heartstream division of Philips Medical Systems, a division of Philips Electronics, the assignee of the present application. I have been involved in the design and development of automatic external defibrillators (AEDs) for over 20 years and am a co-founder of the AED company Heartstream. I am a co-inventor in the present application and the first-named inventor in US Patent 6,134,468 which is of record in the present application.

In my '468 patent I describe an AED system which is suitable for both adults and pediatric patients by use of an energy reduction unit that is used between the patient electrodes and the AED. In column 4 of my '468 patent I describe the two ways in which the energy reduction unit may be used. One way (line 45) is with electrodes ordinarily used on adults. The other (line 47) is with pediatric-specific electrodes that are sized smaller than adult electrodes. As

is known by those skilled in the art, adult electrodes have a total area of at least 150 cm^2 and pediatric-specific electrodes have a total area of at least 45 cm^2 as shown by the attached ANSI/AAMI standards. The present application describes universal electrodes of an intermediate size of 100 cm^2. There is no suggestion in my patent to use electrodes of any other size than the adult or pediatric-specific electrode sizes and one skilled in the art would not read my patent to suggest electrodes of any intermediate size since adult and pediatric-specific electrodes are well known and commonly accepted for their specific patient populations.

Subsequent to the filing of the application for the '468 patent we began patient testing of an energy reduction unit with standard adult elect4odes. The results of those tests showed that this approach was impractical. The adult electrodes were just too large for many pediatric patients. It was this discovery that let, in part, to the development of the present invention.

The various embodiments of energy reduction units I describe in my '468 patent function in two general ways. One is by automatically attenuating the adult energy dose delivered by the AED. The other is by using a presence-detect function which automatically signals to the AED that the patient is a child or infant and that a scaled-down dose should be delivered. I give several examples of how the presence-detect function may be implemented, such as through a separate connector or with an optical, electromagnetic, ID chip, or mechanically-generated signal such as one produced by tripping a switch inside the AED with the connector of the energy reduction unit. In no case do I show or suggest the use of an adult/pediatric mode indicator which can be set by an operator. In my '468 patent I describe the handoff of a

patient from a first responder to an advanced cardiac life support ("ACLS") responder who usually has his or her own manual or semi-automatic defibrillator. The ACLS responder will want to know what dose had been delivered by the AED used by the first responder. An advantage of an adult/pediatric mode indicator is that the ACLS responder can look at the setting of the mode indicator and see immediately and unambiguously the dose that was delivered. The presence-detect embodiments I describe in my patent all operate automatically and internally to the AED, giving the ACLS responder no visual indication of the dose setting and leaving the ACLS responder speculating as to the functioning of an unfamiliar energy reduction unit which operates internally and automatically inside the AED. While we gave some thought to an energy selector switch in our '468 patent, we dismissed the idea as undesirable and employed the automatic internal approach.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Carlton B. Morgan

Date: 1/10/06

SK1

ANSI/AAMI 1993, 16 SEPT
DF 39 APPROVED

American National Standard

Automatic external defibrillators and remote-control defibrillators

Association for the Advancement of Medical Instrumentation

For a voltage of 1.5 times the maximum voltage occurring on the energy storage capacitor, the leakage current flowing between the active part and the insulated backing of the electrode shall not exceed 250μA.

3.3.19.6 DC offset voltage

A pair of electrodes connected gel-to-gel shall, after a 1-minute stabilization period, exhibit an offset voltage no greater than 100mV.

3.3.19.7 Bias current tolerance

The observed dc voltage offset change across a pair of electrodes connected gel-to-gel shall not exceed 100mV when the electrode pair is subjected to a continuous 200 nanoampere (nA) dc current over the period recommended by the manufacturer for the clinical use of the electrodes (but not less than 8 hours).

3.3.19.8 Electrode active area

The minimum active (gel) area of individual self-adhesive electrodes used for adult defibrillation and pacing shall be at least 50 cm^2 and the total area of the two electrodes shall be at least 150 cm^2.

3.3.19.9 Electrode adhesion and contact to patient

The electrode materials and construction shall ensure good adhesion and electrical contact with the patient when the electrodes are placed properly. The characteristics of the adhesive (peel strength, setting time, response to perspiration, effect of temperature of these characteristics) should be available from the vendor.

3.3.19.10 Packaging and shelf life

The device shall be manufactured and packaged in such a way that all requirements of this standard will be met up to the expiration date, and under the storage conditions specified by the manufacturer. At a minimum, electrodes shall comply with all performance specifications after storage of 1 year at temperatures in the range of 15° C to 35° C, and/or after 12 hours exposure to temperatures ranging from -30° C to +65° C (electrodes shall be returned to a temperature in the 15° C to 35° C range before the specifications test is performed).

3.3.19.11 Universal function electrodes

If the electrodes are designed and intended for use in all three modes, i.e., monitoring and defibrillation, and optionally pacing, the following requirements apply:

a) The electrode package shall clearly identify all functions that the electrode will perform.

large dc offsets.

3.3.19.12 Cable length

The electrode cables shall have an extended length of at least 2 meters.

3.3.20 Event documentation

3.3.20.1 Purpose

The purpose of event documentation is to allow medical control authority to:

a) identify whether the device was operated correctly by the user;

b) determine the performance of the device, as a conventional manually operated defibrillator, during clinical use (if the device can operate in the manual mode);

c) determine the performance of the device, as an automatic or semiautomatic defibrillator, during clinical use.

3.3.20.2 Methods of documentation

Event documentation may be achieved by magnetic tape cassettes, solid-state electronic storage modules or cards, or other functionally equivalent means. Retrospective review of stored information may be performed using either the AED or an accessory system.

3.3.20.3 Information content of event documentation

The information content shall be sufficient to allow full retrospective review of the event by the medical control authority. For that purpose, information recorded and reported should include the following:

a) date of the clinical use;

b) device-specific information including device serial number and software revision level if applicable;

c) time when the device was turned on. This time serves as a zero time reference. All subsequent events may be timed in either absolute or elapsed time;

d) time when the electrodes were applied to the patient;

e) initial rhythm;

f) each time analysis was initiated, rhythm during analysis period and result of the analysis (shock indicated or not);

g) time of each shock, nominal delivered energy selected (by the device or the operator), and, optionally, other discharge parameters (e.g., peak current, impedance);

American National Standard

ANSI/AAMI DF2—1996
(Revision of ANSI/AAMI DF2—1989)

Cardiac defibrillator devices

Developed by
Association for the Advancement of Medical Instrumentation

Approved 29 April 1996 by
American National Standards Institute, Inc.

Abstract: This standard provides minimum labeling, performance, and safety requirements for cardiac defibrillator devices. Also included are referee test methods by which compliance can be verified.

Keywords: cardioversion, defibrillation, synchronized cardioversion, ventricular fibrillation

4.3.15.2 AC large signal impedance

The impedance of an electrode pair connected gel-to-gel, in series with a 50-ohm load and measured at E_{MAX}, shall not exceed 3 ohms.

4.3.15.3 Combined offset instability and internal noise

A pair of electrodes connected gel-to-gel shall generate, after a 1-minute stabilization period, a voltage no greater than 100 μV peak-to-peak in the pass band of 0.5 to 40 Hz, for a period of 5 minutes following the stabilization period.

4.3.15.4 Defibrillation overload recovery

The potential of a pair of electrodes connected to a 50-ohm test load and subjected to three E_{MAX} shocks at 1-minute intervals shall not exceed 400 mV at 4 seconds and 300 mV at 60 seconds after the last shock delivery.

4.3.15.5 Biological response

The electrode shall be biocompatible. For this application, with the electrode in continuous contact with the skin for the maximum duration specified by the manufacturer, biocompatibility requires evaluation of cytotoxicity, skin irritation, and skin sensitization.

4.3.15.6 DC offset voltage

A pair of electrodes connected gel-to-gel shall, after a 1-minute stabilization period, exhibit an offset voltage no greater than 100 mV.

4.3.15.7 Bias current tolerance

The observed DC voltage offset change across a pair of electrodes connected gel-to-gel shall not exceed 100 mV when the electrode pair is subjected to a continuous 200-nanoampere (nA) DC current over the period recommended by the manufacturer for the clinical use of the electrodes (but not less than 8 hours).

4.3.15.8 Electrode active area

The minimum active (gel) area of self-adhesive electrodes used for defibrillation and pacing shall be

each	together	purpose
50 cm^2	150 cm^2	adult transthoracic
15 cm^2	45 cm^2	pediatric (less than 10 kg) trans-chest

4.3.15.9 Electrode adhesion and contact to patient

The electrode materials and construction shall ensure good adhesion and electrical contact with the patient when the electrodes are placed properly. Data on the characteristics of the adhesive (peel strength, setting time, response to perspiration, effect of temperature on these characteristics) should be available from the vendor.

4.3.15.10 Packaging and shelf life

The device shall be manufactured and packaged in such a way that all requirements of this standard will be met up to the expiration date and under the storage conditions specified by the manufacturer. At a minimum, electrodes shall comply with all performance specifications after storage for 1 year at 35° C (95° F). One-year storage may be simulated by accelerated testing at higher temperatures. Electrodes shall comply after storage for 24 hours at -30° C (-86° F) and +65° C (149° F). Electrodes shall be returned to a temperature in the range of 15° C to 35° C before the test for compliance is performed.

4.3.15.11 Universal-function electrodes

If the electrodes are designed and intended for use in all three modes, i.e., monitoring, defibrillation, and pacing, the following requirements apply:

a) The electrode package shall clearly identify all functions that the electrode will perform.

b) The electrode package shall provide specific instructions for the connection, placement, and operation of the electrodes for their various functions.

c) The electrode shall meet all requirements of 4.3.15 after 60 minutes of pacing at the maximum current output and maximum pacing rate through a pair of gel-to-gel electrodes in series with a 50-ohm resistor, unless the ECG amplifier has been designed specifically to compensate for large DC offsets.

4.3.15.12 Cable length

The electrode cables shall have an extended length of at least 2 meters. If coiled cords are used, the extension force shall be 18 newtons (4 lb) or less per paddle electrode at a distance of 2 meters.

4.3.16 Electrical risk currents

Chassis leakage, defibrillation electrode source, and sink currents shall be in accordance with 2.4, the American National Standard *Safe Current Limits for Electromedical Apparatus*, (with isolated patient connection), except that the allowable sink and source leakage current per paddle electrode shall become 100 microamperes for external paddle electrodes and 50 microamperes for internal paddle electrodes. These patient leakage currents shall be measured with the output switching device in both the quiescent and the activated condition.

4.3.17 Synchronized discharge

Synchronized discharge is not a required feature of a defibrillator. A defibrillator and a monitor are needed to perform synchronized cardioversion. It is strongly recommended that the defibrillator and the monitor be integrated into a single instrument to ensure proper interfacing.

The operator shall be made aware, in the manual as a minimum, that ECG acquisition should be accomplished through monitor leads or self-adhesive defibrillator electrodes rather than through defibrillator paddle electrodes. A marker shall appear on the monitor screen to mark the times when the monitor has recognized R waves and is producing a signal to trigger defibrillator discharge. The peak of the defibrillator discharge shall occur within 60 mil-